ANIMAL HEALTH INSTITUTE

Representing manufacturers of animal health products

Alexander S. Mathews
President & CEO

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September 13, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 99N-0193 – Supplements and Other Changes to an Approved Application

The ANIMAL HEALTH INSTITUTE ("AHI") submits these comments in response to the Proposed rule published by the Food and Drug Administration in the *Federal Register* on Monday, June 28, 1999, to amend its regulations on supplements and other changes to an approved application to implement the manufacturing changes provision of the Food and Drug Administration Modernization Act of 1997.

AHI is the national trade association representing manufacturers of animal health products – the pharmaceuticals, vaccines and feed additives used in modern food production, and the medicines that keep livestock and pets healthy.

On August 27, 1999 the Pharmaceutical Research and Manufacturers of America (PhRMA) submitted comments to Docket No. 99N-0193 which concluded by recommending that "the proposed rule and draft guidance be withdrawn in order to allow development of a revised proposed rule and associated industry guidance that clearly reflects the intent of Congress as required by the FDA Modernization Act." The Animal Health Institute endorses in its entirety the comments submitted by PhRMA.

Although the proposed rule applies only to human drugs and biologics, AHI is commenting because the Center for Veterinary Medicine (CVM) is believed to be preparing a similar proposal and may be compelled to apply most if not all of the principles described in the proposed rule. The animal drug industry is very pleased with the successful 1996 CVM initiative, "Alternate Administrative Process for the Implementation and Submission of Supplemental Chemistry, Manufacturing and Control Changes (AAP)." In fact, AHI's support of FDAMA was given based on our legal interpretation that FDAMA did not preclude the continuation of the AAP program.

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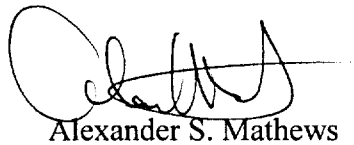
The AAP program succinctly provides a process for determining minor supplemental chemistry, manufacturing and control changes that are reported on a biennial basis. AHI continues to strongly support the concepts embodied in the AAP and is concerned that implementation of the proposed rule would be more burdensome, on both FDA and industry, than the AAP. CVM and AHI member companies have had three years of successful implementation of this program and believe that proposed rule, if applied to animal drugs, would be a major step backwards.

Sincerely,



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